UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/532,263	03/22/2000	Douglas James Hilton	10296A	8294

7590 02/24/2004

Scully Scott Murphy & Presser
400 Garden City Plaza
Garden City, NY 11530

EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/532,263	HILTON, DOUGLAS JAMES	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,8,9,11,12 and 31-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,12 and 31-34* is/are rejected.

7)☒ Claim(s) *8, 9, 11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 2-4, 6-7, 10, 13-30 have been canceled previously. Claims 5, 8-9, 11-12, amended claim 1 (1/2/2004) and new claims 31-34 (1/2/2004) are under consideration.

2. Receipt of Applicant's arguments and amendments filed on 1/2/2004 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 1/2/04:

(i) the objection to the title of the invention for the recitation of novel;

(ii) the objection to the specification for the lack of sequence identifiers in Table 2; and

(iii) the rejection of claims 1, 5 under 35 U.S.C. 112, second paragraph.

4. Applicant's arguments filed on 1/2/2004 have been fully considered but were persuasive in part. The issues remaining and new issues are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph

6. Claims 12, 31-32 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record set forth at pages 3-4 of the previous Office action (9/5/03).

Applicant argues that the genus of the claimed invention is sufficiently described in the specification to convey to one of ordinary skill in the art that Applicant had possession of the

claimed genus of nucleic acids encoding mammalian IL-11 receptor α-chain. Furthermore, Applicant argues that the specification clearly describes the isolation of a nucleic acid encoding human IL-11 receptor α-chain by using murine sequence-derived probes under the conditions recited in claim 12 and that these complete amino acid sequences would convey to one of skill in the art that Applicant was in possession of the claimed nucleic acid sequences. However, contrary to Applicant's arguments, claims 12, 31-32 encompass a genus of nucleic acids encoding polypeptides that comprise nucleic acid sequences encoding IL-11 receptor α-chain isolated from any mammalian species including human, mouse, pig, cow, rat, horse, etc, as well as polynucleotide variants encoding these proteins having one or more amino acid deletions, insertions and/or additions made to SEQ ID NO: 5. The specification and claims do not indicate what are the distinguishing attributes shared by the members of the genus for which the common portion is responsible for functional activity. The specification and claims do not place any limit on the number of amino acids that may be added to the portions since the claims are not limited to the full-length SEQ ID NO:5. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members are permitted.

New claim 31 recites an activity for the polypeptide encoded by the claimed nucleic acid while new claim 32 recites that the polypeptide comprises "SEQ ID NO:1" which is a 5 amino acid sequence. This 5 amino acid sequence is not a sufficient structural limitation and broadly encompasses a nucleic acid encoding a protein comprising this contiguous 5 amino acid sequences recited in the claims and the ability of an oligonucleotide selected from SEQ ID NO:6-10 (which are each 15 nucleotides in length) to hybridize to this nucleic acid. Because of

the presence of the term "comprises" in claim 32, the claim encompasses a nucleic acid encoding a polypeptide comprising SEQ ID NO:1 and therefore the claim encompasses nucleic acids encoding polypeptide embodiments encompassing any other 418 amino acid sequences or more in addition to these 5 contiguous amino acids. The number of nucleotide embodiments encoding polypeptide embodiments in this case are over 5×10^{200}.

Applicant argues that while the genus encompasses a large number of embodiments, it is not unpredictably variant and that variance is limited to that tolerated by the genetic variance in coding sequence for a particular amino acid in the disclosed sequence. Furthermore, Applicant argues that the present specification also describes the structural characteristics of mammalian IL-11 receptor α-chains, particularly by providing examples of the common structural features shared by a murine IL-11 receptor α-chain and a human IL-11 receptor α-chain, including the IgG domain, the haemopoietin domain, the conserved cysteines and the WSXWS motif as well as the functional features of mammalian IL-11 receptor α-chains. However, contrary to Applicant's arguments, although the specification states some of the functional features of mammalian IL-11 receptor α-chains, the specification does not provide a written description as to what changes should be made which are tolerated by the genetic variance in coding sequence for a particular amino acid in the disclosed sequence. The structural feature recited in claim 32 is insufficient to describe the genus of nucleic acid molecules claimed. Structural features that could distinguish the nucleic acid encoding the IL-11 receptor α-chains in the genus from others in the protein class are missing from the disclosure. No common structural and functional attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is

needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, polynucleotides encoding SEQ ID NOs: 5, alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus of mammalian IL-11 receptor α-chain.

Applicant argues that the two full-length species are representative of the claimed genus. However, contrary to Applicants arguments, even though a genetic code table would correlate the human and mouse amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the members of a genus comprising only small portions of the full-length sequence. Thus, at the time the application was filed, nucleic acid sequences encoding the amino acid sequences of other mammalian IL-11 receptor α-chain i.e. rodent, canine, feline, etc., other than human and mouse were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention.

7. Claims 1, 5, 12, 31-34 also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule encoding a IL-11 receptor polypeptide as set forth in SEQ ID N0:5, does not reasonably provide enablement for a nucleic acid molecule encoding a mammalian IL-11 receptor α-chain said nucleic acid and further defined by the ability of an oligonucleotide selected from SEQ ID N0S:6-10 to hybridize under the conditions recited in claim 12. The specification does not enable any person skilled in

the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is maintained for reasons of record set forth at pages 5-7 of the previous Office action (9/5/03).

The declaration submitted with the response on April 9, 2003 and again submitted with the response of January 2, 2004, under 37 CFR 1.132 filed is sufficient and nonpersuasive to overcome the rejection of claims 12, 31-32 based upon 35 U.S.C. 112, first paragraph because the declaration reiterates and presents Applicants arguments in declarative form. In the declaration Dr. Hilton argues that a series of oligonucleotides were generated encompassing the nucleotide sequence encoding the signature motif WSXWS and the murine IL-11Rα was cloned, and then employing hybridization of murine IL-11Rα cDNA, the human IL-11Rα was cloned. However, contrary to the assertion in the declaration, the limitations argued (WSXWS) are not recited in independent claim 12. Furthermore, the issue here is that Applicants have not taught how to make and use the various hybridization variants that retain the features of IL-11Rα from the various mammalian species.

The claimed genus of nucleic acids encoding IL-11Rα polypeptides encompasses (1) variants that share activity, however, the specification does not teach how to make a polynucleotide sequence encoding a polypeptide having an amino acid sequence less than SEQ ID NO:5, that would share those activities and (2) variants that do not share activity, however, the specification does not teach how to use these variants that do not share IL-11Rα activity. Applicants are not claiming polynucleotide sequences that are "probes" but polynucleotide sequences that encode IL-11Rα proteins. The specification only enables polynucleotides

encoding IL-11Rα proteins of amino acid sequences set forth in SEQ ID NO:5 and is not enabled for a polynucleotide encoding a polypeptide having an amino acid sequence anything less than what is disclosed in SEQ ID NO:5, the claimed polypeptides having specific characteristics (the IL-11Rα interacts with gp130 protein to mediate IL-11 induced proliferative or differentiative response).

The issue in the instant case is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. Furthermore, the instant specification does not provide the guidance needed to use these polynucleotides as claimed. Even if Applicants recited a functional limitation for the IL-11Rα polypeptide in the instant claims, Applicants have not taught how to make the instant polynucleotides encoding IL-11Rα polypeptides wherein the polynucleotide hybridizes to the complement of SEQ ID NO:4 under the conditions recited in claim 1. The instant specification does not teach which polynucleotides encoding polypeptides would predictably be associated with the IL-11Rα function. There is no guidance in the specification for how to make and use polynucleotides encoding a protein having the amino acid sequence anything less than that disclosed in SEQ ID NO:5.

The standard that routine experimentation is required to identify the numerous embodiments is a position that has been routinely dismissed by the courts, as shown by the CAFC decision in Genentech, Inc. v. Novo. Nordisk, 42 USPQ2d, 100 (CAFC 1997), in which the decisions in In re Fisher, Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., and In re Wands were considered as the controlling precedents in determining enablement issues where protein

and recombinant DNA issues are concerned. These decisions have been relied upon in the instant rejection and by the Court because they show that the judicial interpretation of the first paragraph of 35 U.S.C. § 112 requires that the breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work than not, without actually making and testing them, then the instant application does not support the breadth of the claims.

Further, In re Wands determined that the repetition of work which was disclosed in a patent application as producing a composition containing an antibody, which is a naturally-occurring compound, did not constitute undue experimentation even if the antibody produced thereby was not identical to those that were disclosed in that application. The instant claims are not limited to naturally-occurring compounds and the instant specification does not provide a description of a repeatable process of producing a polynucleotide encoding a IL-11Rα polypeptide as set forth in claims 1 and 12. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those amino acid residues of the disclosed naturally-occurring protein, which are required for functional and structural integrity of the

protein. It is this additional characterization of the nucleic acid encoding the disclosed protein that is required in order to obtain the structural data needed to permit one to produce the claimed polynucleotide encoding a protein which meets the structural requirements of the instant claims that constitutes undue experimentation.

With respect to new claim 33 which recites s function for the protein encoded by the claimed nucleic acid molecule and new claim 34 which recites that the protein encoded by the claimed nucleic acid molecule comprises the 5-amino acid sequence set forth in SEQ ID NO:1, the instant specification does not provide the guidance needed to use these nucleic acid molecules as claimed. Even if Applicants recite a functional limitation for the polypeptide in the instant claims, Applicants have not taught how to make the instant nucleic acid molecule encoding polypeptides with the stretch of 5 contiguous amino acids as recited in claim 34. The instant specification does not teach which nucleic acid molecules encoding polypeptides would predictably be associated with that function. There is no guidance in the specification for how to make and use nucleic acids encoding proteins having an amino acid sequences anything less than that disclosed in SEQ ID NO:5.

8. Claims 1, 5, 33-34, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record set forth at pages 8-9 of the previous Office action (9/5/03).

For all the same reasons recited in paragraph 6 above, claims 1, 5, 33-34 are also rejected under the written description requirement of 35 U.S.C. 112, first paragraph because the instant specification provides a written description only for a nucleic acid encoding an α-chain of human IL-11 receptor of amino acid sequence set forth in SEQ ID NO:5.

9. Claims 1, 5, 33-34 are rejected under 35 U.S.C. 1 12, first paragraph, because the specification, while being enabling for a nucleic acid molecule encoding an α-chain of human IL-11 receptor comprising the amino acid sequence set forth in SEQ ID N0:5, does not reasonably provide enablement for a nucleic acid molecule encoding an α-chain of human IL-11 receptor that hybridizes to the complementary form of SEQ ID NO:4 as recited in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is maintained for reasons of record set forth at pages 9-10 of the previous Office action (9/5/03).

For all the same reasons recited in paragraph 7 above, claims 1, 5, 33-34 are also rejected under the enablement requirement of 35 U.S.C. 112, first paragraph because the instant specification is enabling only for a nucleic acid encoding an α-chain of human IL-11 receptor of amino acid sequence set forth in SEQ ID NO:5.

Claim Rejections - 35 USC § 112, second paragraph

10. Claims 32 and 34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32, line 2, is confusing because it recites both the 5 amino acid sequence and the SEQ ID NO: for the 5 amino acid sequence, which recitation is redundant. It is suggested that the recitation of the 5 amino acid sequence be deleted and only the SEQ ID NO be recited to prevent printer errors.

Similarly, claim 34, line 2, is confusing because it recites both the 5 amino acid sequence and the SEQ ID NO: for the 5 amino acid sequence, which recitation is redundant

Conclusion

No claim is allowed.

Claims 8-9, 11, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
January 22, 2004